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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GILPIN, CRYSTAL M

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/23/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,222

Applicant(s)

SHIMIZU ET AL. 

Examiner

Crystal M Gilpin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-47 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 7, 9, 11, 12, 14, 15, 18-20, 21, 24, 26, 28-31, 33-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Solar (USPN 5,403,341).

Regarding claims 1-5, 7, 9, 20, 24, 28-31, 33, 34 Solar discloses a medical device comprising a catheter (Fig. 4a, Ref.# 30) with an expandable balloon (Fig. 4a, Ref. #38); an endoprosthesis that comprises a stent (Fig. 4a, Ref.# 10) with a first and second end; and an expandable tubular sleeve extending over the first and second ends of the endoprosthesis and a portion of the balloon (Fig. 4a, Ref. #40) that is configured to separate into at least three portions. Solar discloses that the sleeve comprises a plurality of separation portions (Column 3, Lines 6-9) that are over the stent (Fig. 4a). Solar further discloses that the endoprosthesis has an

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outer surface which the sleeve extends over (Fig. 4a); and that the balloon has a sleeve portion that is over the catheter (Fig. 4a, Ref.# 38) and is attached to the sleeve portion that covers the stent.

Regarding claims 11, 12 and 21, Solar discloses that the sheath or sleeve can be made of a polymer such as polyurethane, or latex (Column 3, lines 9-20).

Regarding claims 14, 15 and 26, Solar discloses that the sheath or sleeve is perforated and defines lateral openings when expanded (Fig. 4c).

Regarding claim 18, Solar discloses that the sleeve includes portions that are configured to move away from the prosthesis after the sleeve separates (Column 9, Lines 5-19).

Regarding claim 19, Solar discloses that the endoprosthesis is embedded in the sleeve.

Regarding claims 35-39, Solar discloses a method that comprises a catheter comprising an expandable balloon, an expandable endoprosthesis, and expandable sleeve and separating the sleeve into a plurality of portions (Fig. 4a). Solar further discloses that the sleeve is separated in a sequence of events (Columns 7-9) into three portions (Fig. 4c) and the endoprosthesis and sleeve are separated.

Regarding claim 40, it is inherent that the sleeve defines an opening that is aligned with body lumen because as the sleeve is inserted into the body lumen it will become aligned with the body lumen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6, 8, 16, 17, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solar (USPN 5,403,341) in view of DiCaprio (USPN 6,432,129).

Regarding claims 6, 8, 23 and 25, Solar teaches of a medical device comprising a catheter, balloon, expandable endoprosthesis and sleeve, however he lacks the teachings of the sleeve being attached to a tapered portion of the balloon and to the catheter. DiCaprio teaches of a stent delivery system where the sleeves are attached to the catheter (Fig. 1, Ref. # 46 and 48 and Column 5, Line 53-Column 6, Line 2), to hold the sleeves in place, and to the tapered portion of the balloon (Ref.# 16 and 18), to help reduce the diameter of the balloon after the stent has been deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Solar to have the sleeves attached to the catheter and to the balloon, as taught by DiCaprio for the purpose of holding the sleeve in place during implantation and to assist in reducing the diameter of the balloon after the stent has been deployed.

Regarding claims 16 and 17, Solar lacks the teaching of a pressure or level of expansion that must be met in order to separate the sleeve. DiCaprio teaches of a stent delivery system with rounded balloon ends so that the stent will expand and the sleeve will be able to disengage at a pressure between 4 and 10 ATM and at an 11 percent increase in end length. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Solar to have the sleeve separate at a predetermined pressure or level expansion so that the sleeve can be properly retracted.

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3. Claims 13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solar (USPN 5,403,341) in view of Bigus et al. (US20020052640).

Regarding claims 13 and 22, Solar lacks the teaching of the sleeve having a therapeutic agent. Bigus et al. teach that of a self-expanding stent with a sheath or sleeve that includes a therapeutic agent for delivery within the body lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Solar to have a sleeve with a therapeutic agent, as taught by Bigus et al., for the delivery of anti-coagulation drugs.

4. Claims 41-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiCaprio (USPN 6,432,129) in view of Solar (USPN 5,403,341).

Regarding claim 41, DiCaprio teaches of a stent delivery system comprising a catheter (Fig. 1, Ref. # 12), an expandable sleeve attached to the catheter (Fig. 1, Ref. # 48) and an expandable endoprosthesis attached to the catheter and the sleeve (Fig. 1, Ref. #30), however DiCaprio lacks the teaching of the sleeve being able to separate into a plurality of portions. Solar teaches of a stent with a perforated sheath that can be separated into a plurality of portions for easy removal from the underlying endoprosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of DiCaprio to have the sleeve capable of being separated into a plurality of portions, as taught by Solar for the purpose of easily removing the sleeve portions from the endoprosthesis and the body lumen.

Regarding claims 42 and 45, DiCaprio teaches that the catheter comprises an expandable balloon (Fig. 1, Ref. # 14) upon which the endoprosthesis and sleeve are carried, where the sleeve covers the ends of the endoprosthesis.

Regarding claim 43, DiCaprio teaches that the endoprosthesis could be self-expanding (Column 1, Lines 32-35).

Regarding claim 47, DiCaprio lacks the teaching of the sleeve being a tubular member due to the taper of the balloon. Solar teaches that the sleeve is a tubular member (Fig. 4a, Ref. # 40) so that it fits snugly over the balloon and stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of DiCaprio to have the sleeve shaped as a tubular member in order to have it securely fit over the balloon and the stent.

Regarding claim 44 DiCaprio discloses a sleeve that covers the ends of the endoprosthesis.

DiCaprio does not disclose expressly that the sleeve covers the entire endoprosthesis.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the sleeve cover the entire endoprosthesis because Applicant has not disclosed that covering the entire endoprosthesis provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the ends covered because sufficient retaining force for the stent would be provided.

Therefore it would have been an obvious matter of design choice to modify the invention of DiCaprio to obtain the invention as specified in claim 44.

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5. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiCaprio (USPN 6,432,129) in view of Solar (USPN 5,403,341) and in further view of Armstrong et al. (USPN 6,315,792).

Regarding claim 46, DiCaprio teaches of a stent delivery system comprising a catheter (Fig. 1, Ref. # 12), an expandable sleeve attached to the catheter (Fig. 1, Ref. # 48) and an expandable endoprosthesis attached to the catheter and the sleeve (Fig. 1, Ref. #30), however DiCaprio lacks the teaching of a sheath to cover the sleeve. Armstrong et al. teach of a stent with a covering sheath (Fig. 23A-23C, Ref. # 190) that allows the balloon to be inflated at two different pressures (Column 12, Lines 24-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of DiCaprio to have the medical device, including a stent and a sleeve, covered by sheath to allow the balloon and the sheath to inflate and separate, respectively, at different pressures.

Allowable Subject Matter

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg

April 21, 2003



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